

Manufacturer:
Sparmed ApS/CVR.No.: 30898575
Ryttermarken 2, 3520 Farum, Denmark



ID: COA-07608

Certificate of Analysis

Date of issue: 21.06.2016
Product ID: Oosafe® Plasticware: OOPW-FW03
LOT No.: 07608
Expiry Date: 10/2020
Storage conditions: 20⁰C, dry room, no exposal to sun-light
Quality Assurance:

Proven non-embryotoxic by Mouse Embryo Assay Test. 100% embryo development to the expanded blastocyst stage within 96hours. **PASS**
Proved stable human sperm motility: ≥70% sperm motility after 24hours proven. **PASS**
Proven non-toxic by Limulus Amebocyte Lysate (LAL) test. Pass criteria <0.03 EU/device **PASS**
Proven RNase DNase test FREE- **PASS**
Sterilization by gamma irradiation. Delivered irradiation dose: 8.6kGy-9.5kGy. Specified irradiation dose: 8.0kGy-10.0kG- **PASS**

Quality control according to the ISO 13485:2012

Final approval:
Stamp:

A handwritten signature in blue ink, appearing to read 'C. Nielsen', is written over a faint, circular stamp.

Camilla Inesa Nielsen
Regulatory Affairs Manager

QC

Certificate of Analysis

REQUESTED BY: SparMED ApS (Ryttermarken 2, Farum 03520 Denmark)

ASSAY REQUESTED BY CUSTOMER: LAL - Limulus amebocyte lysate assay

INTERNAL NUMBER: LAL.006.423.2016
DATE: 14/06/2016 - 21/06/2016

DESCRIPTION OF TEST PRODUCT: Oosafe Plastcware 4-well dish, Treated Surface + Oosafe Plastcware 6-well dish
REF: OOPW-FW03 / OOPW-SW02
LOT NUMBER: 07608 / 07610
EXP. DATE: 31/10/2020

PROTOCOL:

Samples were fully loaded and exposed for 60 min to pre-warmed endotoxin-free water. Afterwards, the extracted water was analyzed following USP <85> Bacterial Endotoxins Test and USP <161> Transfusion and infusion assemblies and similar medical devices protocols.

BACTERIAL ENDOTOXINS

Chromogenic kinetic method

Result	<0.005 EU/mL
Detection limit	0.005 EU/mL
Method	USP <85> Bacterial Endotoxins Test USP <161> Transfusion and infusion assemblies and similar medical devices
Devices tested	3
Volum of the rinse	26 ml
Endotoxin allowed	2.31 EU/mL

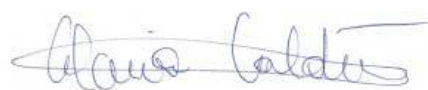
The **Oosafe Plastcware 4-well dish, Treated Surface + Oosafe Plastcware 6-well dish** sample with lot **07608 / 07610** did fulfill mandatory LAL test criteria.

Nuno Costa-Borges, PhD



Scientific Director

Gloria Calderón, PhD



Quality Assurance

QC

Certificate of Analysis

REQUESTED BY: SparMED ApS (Ryttermarken 2, Farum 03520 Denmark)

ASSAY REQUESTED BY CUSTOMER: MEA - Standard Mouse embryo assay

TYPE OF ASSAY: Direct

INTERNAL NUMBER: MEA.006.422.2016

DATE: 14/06/2016 - 18/06/2016

DESCRIPTION OF TEST PRODUCT: Oosafe Plastcware 4-well dish, Treated Surface + Oosafe Plastcware 6-well dish

REF: OOPW-FW03 / OOPW-SW02

LOT NUMBER: 07608 / 07610

EXP. DATE: 31/10/2020

PROTOCOL:

Test dishes were prepared in duplicate with previously tested culture medium microdroplets overlaid with mineral oil, and equilibrated overnight prior to use under optimal temperature, %CO₂ and %O₂ conditions. Fresh 1-cell stage mouse embryos were collected from F1 hybrid females (B6/CBA) crossed with males from the same genetic background, washed thoroughly and cultured in test culture dishes up to Day 5 (96 hours). Control group was prepared following the same set-up and conditions, and embryos cultured in parallel using previously tested dishes. Embryo development of test and control group was followed every 24 h and photos were taken and included in this report (annex I).

CONTROL AND TEST ASSAY RESULTS:

Embryo developmental rates of control and tested group.

Embryo development rates					
	n	Day 2 Two-cell stage n (%)	Day 5 Blastocyst stage n (%)	Good Quality (morphology) Blastocysts n (%)	Result
Control	15	15 (100)	14 (93.33)	12 (85.71)	Passed*
Oosafe Plastcware 4-well dish, Treated Surface + Oosafe Plastcware 6-well dish (Lot:07608 / 07610)	21	21 (100)	20 (95.24)	18 (90)	Passed*

SUMMARY OF OBSERVATIONS: All test and control embryos were selected randomly from a common pool and cultured at 37.3°C with a tri-gas atmosphere with optimal %CO₂ and %O₂. Acceptance criteria of this standard test is ≥80% of mouse embryos must develop to the expanded blastocyst stage and pass a visual morphological examination of the inner cell mass (ICM) and trophectoderm (TE) cells.

* More than 80% of the test group embryos developed to the expanded blastocyst stage within 5 days, fulfilling acceptance criteria for this test.

Nuno Costa-Borges, PhD



Scientific Director

Gloria Calderón, PhD



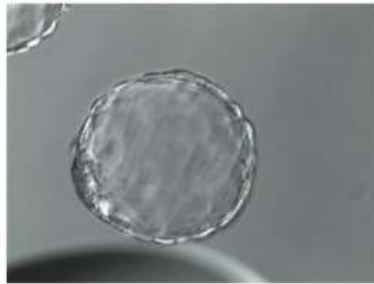
Quality Assurance

Annex I
Control

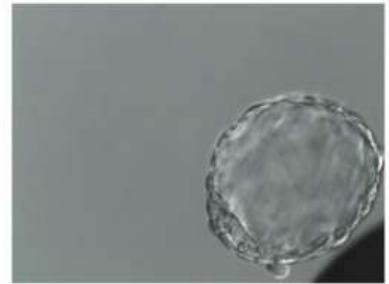
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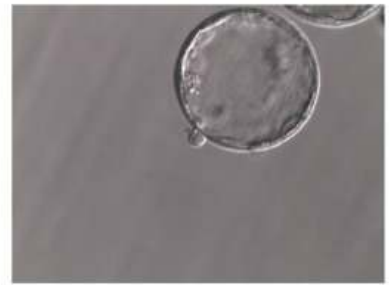
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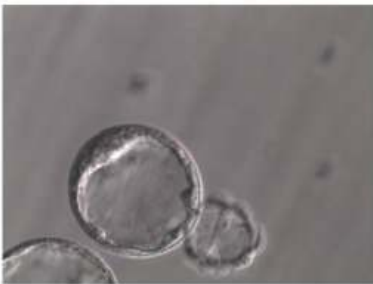
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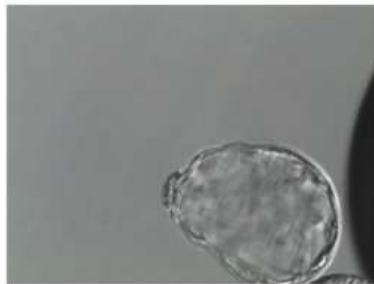
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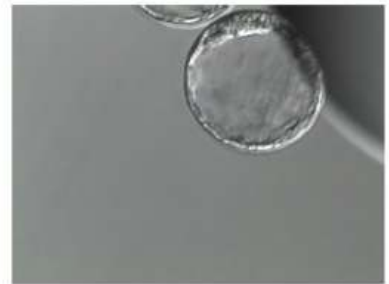
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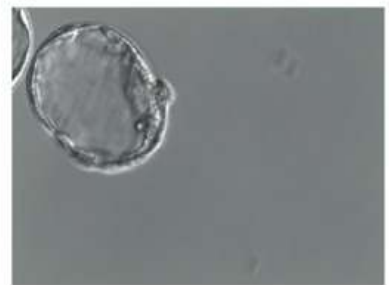
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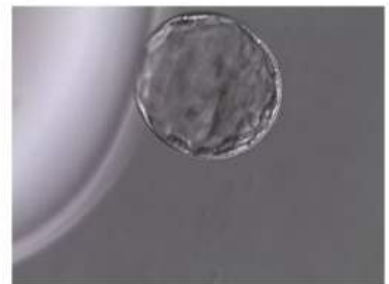
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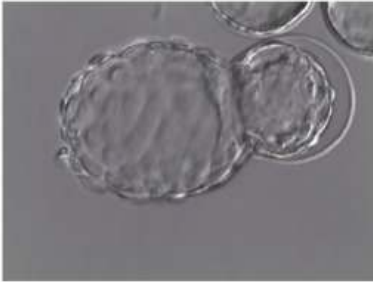


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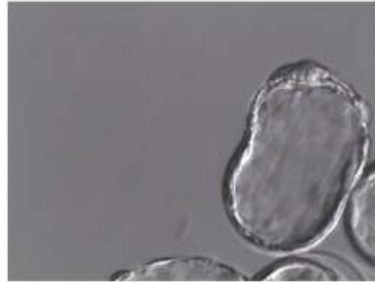


Oosafe Placware 4-well dish, Treated Surface + Oosafe Placware 6-well dish
 (REF: OOPW-FW03 / OOPW-SW02 ; Lot: 07608 / 07610)

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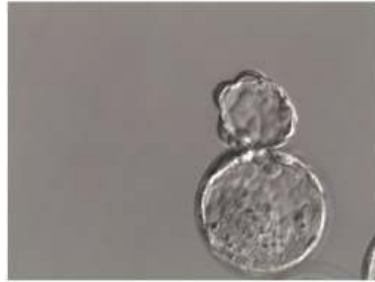
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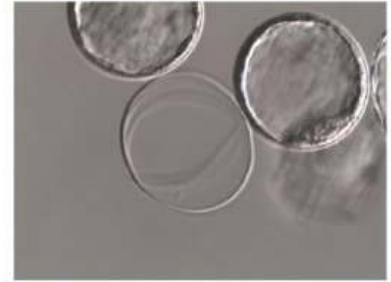
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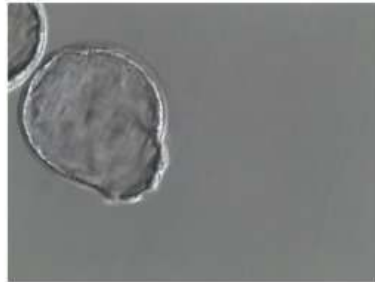
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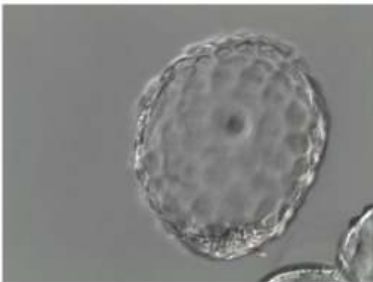
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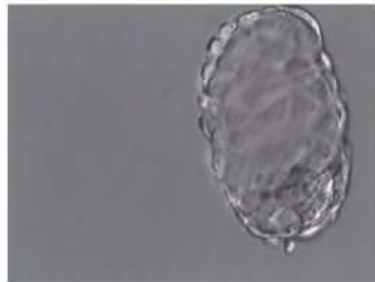
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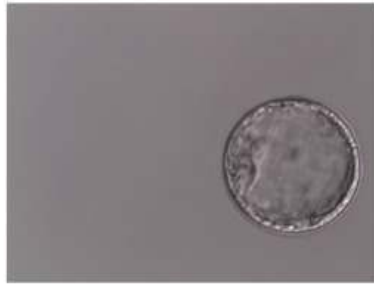


Oosafe Plasticsware 4-well dish, Treated Surface + Oosafe Plasticsware 6-well dish
 (REF: OOPW-FW03 / OOPW-SW02 ; Lot: 07608 / 07610)

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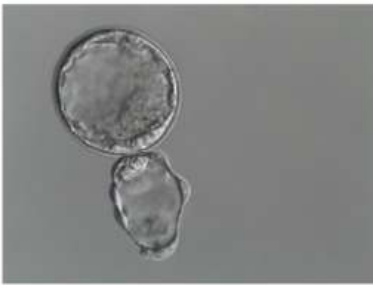
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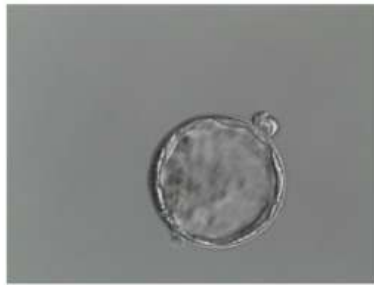
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#18, 18/06/2016 11:32:54



#19, 18/06/2016 11:33:00



#20, 18/06/2016 11:33:25



#21, 18/06/2016 11:33:28



Annex II

CONTROL AND TEST ASSAY RESULTS:

Average no. of total cells in blastocysts from control and test groups.

	Total cell number	
	n	Average no. of cells per blastocyst (+/- SD)
Control	14	133.7 (+/- 28)
Oosafe Placware 4-well dish, Treated Surface + Oosafe Placware 6-well dish (lot.:07608 / 07610)	20	166.2 (+/- 33.9)

QC

Certificate of Analysis

REQUESTED BY: SparMED ApS (Ryttermarken 2, Farum 03520 Denmark)

ASSAY REQUESTED BY CUSTOMER: SMA - Sperm motility assay

TYPE OF ASSAY: Indirect

INTERNAL NUMBER: SMA.006.424.2016

DATE: 15/06/2016 - 16/06/2016

DESCRIPTION OF TEST PRODUCT: Oosafe Plastcware 4-well dish, Treated Surface + Oosafe Plastcware 6-well dish

REF: OOPW-FW03 / OOPW-SW02

LOT NUMBER: 07608 / 07610

EXP. DATE: 31/10/2020

PROTOCOL:

A sperm sample was processed in duplicate using silica-based density gradients (95%, 70% and 45% concentration) and test products incubated with previously tested medium for 60 min at 37°C. Afterwards, the resulting sperm preparation was incubated with the extracted medium (test group) or control tested medium (control group), to achieve a final concentration of approximately 2 million progressive sperms per milliliter. Test and control groups were incubated in parallel in the same incubator chamber at 37.3°C and optimal %CO₂ and %O₂, and sperm motility assessed at 0, 4, 8 and 24 hours after processing. Sperms were classified according to their mobility patterns in progressive (PS), non-progressive (NPS) and immobile (IS).

CONTROL AND TEST ASSAY RESULTS:

Motility evaluation of control and tested group.

	Motility evaluation											
	0 hours			4 hours			8 hours			24 hours		
	PS%	NPS%	IS%	PS%	NPS%	IS%	PS%	NPS%	IS%	PS%	NPS%	IS%
Control	93.90	3.90	2.20	92.00	3.35	4.65	89.65	5.05	5.30	69.85	9.20	15.85
Oosafe Plastcware 4-well dish, Treated Surface + Oosafe Plastcware 6-well dish (lot.:07608 / 07610)	91.65	3.10	5.25	93.75	3.65	2.60	82.00	7.15	10.85	72.20	12.80	14.30

* progressive (PS), non-progressive (NPS) and immobile (IS)

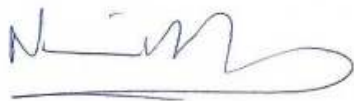
Sperm motility index (SMI) values:

	Sperm motility index			
	0 hours	4 hours	8 hours	24 hours
Oosafe Plastcware 4-well dish, Treated Surface + Oosafe Plastcware 6-well dish (lot.:07608 / 07610)	0.98	1.02	0.91	1.03

SUMMARY OF OBSERVATIONS: Test and control samples were incubated in the same incubator at 37.3°C with a tri-gas atmosphere with optimal %CO2 and %O2.

Sperm motility index (SMI) corresponds to the value obtained by dividing the percentage of motile sperms in the test group by the percentage of motile sperms in the control group. Values <0.75 by 8 h post incubation are considered as indicators of poor assisted reproduction outcomes and this cut-off value has been used as reference to indicate sperm toxicity.

Nuno Costa-Borges, PhD



Scientific Director

Gloria Calderón, PhD



Quality Assurance